No. 06-1539

In the Supreme Court of the United States

MICHAEL MARKOVICH AND MELISSA MARKOVICH,
PARENTS OF ASHLYN M. MARKOVICH,
PETITIONERS

v.

MICHAEL O. LEAVITT,
SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the statute of limitations under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-16(a)(2), commences upon the occurrence of the first symptom of an alleged vaccine-related injury, even if the child's parents do not fully appreciate the medical significance of the symptom at that time.

TABLE OF CONTENTS

Page

Opinions below 1
Jurisdiction 1
Statement 2
Argument 8
Conclusion 16

TABLE OF AUTHORITIES

Cases:

Block v. *North Dakota ex rel. Bd. of Univ. & Sch. Lands*, 461 U.S. 273 (1983) 12

Bradley v. *Secretary of the Dep't of Health & Human Servs.*, 991 F.2d 1570 (Fed. Cir. 1993) 15

Brice v. *Secretary of Health & Human Servs.*, 240 F.3d 1367 (Fed. Cir.), cert. denied, 534 U.S. 1040 (2001) 7, 12, 14

Setnes ex rel. Setnes v. *United States*, 57 Fed. Cl. 175 (2003) 7, 12, 14

Shalala v. *Whitecotton*, 514 U.S. 268 (1995) 7, 9, 10, 14

Vessels v. *Secretary of the Dep't of Health & Human Servs.*, 65 Fed. Cl. 563 (2005) 13

Statutes and regulation:

National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (42 U.S.C. 300aa-1 *et seq.*) 2

42 U.S.C. 300aa-10(a) 2

42 U.S.C. 300aa-11(a) 3

42 U.S.C. 300aa-11(c)(1)(C)(i) 2, 9, 10

Statutes and regulation–Continued: Page

42 U.S.C. 300aa-11(c)(1)(C)(ii)(I)-(II) 3
42 U.S.C. 300aa-12(d)(3) 3
42 U.S.C. 300aa-12(e)(1) 3
42 U.S.C. 300aa-12(f) 3
42 U.S.C. 300aa-13(a)(1) 3
42 U.S.C. 300aa-13(a)(1)(A) 2
42 U.S.C. 300aa-13(a)(1)(B) 2
42 U.S.C. 300aa-14(a) 2
42 U.S.C. 300aa-15(a)-(e) 3
42 U.S.C. 300aa-15(i) 2
42 U.S.C. 300aa-16(a)(2) ..... *passim*
42 U.S.C. 300aa-16(c) 3
42 U.S.C. 300aa-21(a) 3
26 U.S.C. 9510 2
42 C.F.R. 100.3(a) 2

Miscellaneous:

H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1 (1986) 2

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-17) is reported at 477 F.3d 1353. The opinion of the Court of Federal Claims (Pet. App. 18-42) is reported at 69 Fed. Cl. 327. The opinion of the special master (Pet. App. 43-87) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 20, 2007. The petition for a writ of certiorari was filed on May 18, 2007. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Congress enacted the National Childhood Vaccine Injury Act of 1986 (Vaccine Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (42 U.S.C. 300aa-1 *et seq.*), to promote national childhood immunization programs by establishing a tax-based federal compensation scheme for children injured by vaccines, thereby reducing the number of traditional tort actions filed against vaccine manufacturers. H.R. Rep. No. 908, 99th Cong., 2d Sess. Pt. 1, at 3-5 (1986). The Vaccine Act established a National Vaccine Injury Compensation Program (Program), funded by an excise tax on vaccines, to provide compensation for vaccine-related injuries and deaths. See 42 U.S.C. 300aa-10(a), 300aa-15(i); 26 U.S.C. 9510.

Petitioners under the Program may establish a right to compensation in either of two ways. First, the Vaccine Act presumes that an injury was caused by a vaccination, and is therefore compensable, if the person who suffered the injury "sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table," 42 U.S.C. 300aa-14(a); 42 C.F.R. 100.3(a), and "the first symptom or manifestation of the onset or of the significant aggravation" of the injury "occurred within the time period after vaccine administration set forth in the Vaccine Injury Table." 42 U.S.C. 300aa-11(c)(1)(C)(i); see 42 U.S.C. 300aa-13(a)(1)(A). The presumption of causation may be rebutted by evidence that the injury was "due to factors unrelated to the administration of the vaccine." 42 U.S.C. 300aa-13(a)(1)(B). Second, if the injury does not appear in the Vaccine Injury Table, a petitioner may nonetheless obtain compensation by demonstrating, by a preponderance of the evidence, that the injury in fact

"was caused by" a vaccination. 42 U.S.C. 300aa-11(c)(1)(C)(ii)(I)-(II), 300aa-13(a)(1). A petitioner under the Program need not demonstrate that the vaccine was defective or that its manufacturer was negligent.

The compensation available under the Program includes unreimbursed medical expenses, rehabilitation, special education, vocational training, residential and custodial care, special equipment, lost earnings, pain and suffering, and attorneys' fees. 42 U.S.C. 300aa-15(a)-(e). A petitioner dissatisfied with a Program award may reject it and litigate the claim under state tort law, subject to certain limitations. 42 U.S.C. 300aa-11(a), 300aa-21(a). Applicable state statutes of limitation are tolled during the pendency of a petition under the Act. 42 U.S.C. 300aa-16(c).

In the case of a vaccine-related injury for vaccines administered after October 1, 1988, "no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury." 42 U.S.C. 300aa-16(a)(2). Petitions initially are reviewed by a special master of the United States Court of Federal Claims. 42 U.S.C. 300aa-12(d)(3). The parties may seek review of the decision of the special master before the Court of Federal Claims, 42 U.S.C. 300aa-12(e)(1), and may appeal from that judgment to the United States Court of Appeals for the Federal Circuit, 42 U.S.C. 300aa-12(f).

2. On July 10, 2000, petitioners' two-month-old child, Ashlyn Markovich, received vaccinations for diphtheria, tetanus, pertussis, polio, and influenza at the Fairview Cedar Ridge Clinic in Apple Valley, Minnesota. Later that day, she experienced an episode in which her eyes

rapidly blinked or fluttered. Petitioners noticed the episode, but assumed that she was simply tired. Pet. App. 3, 21-22 & n.2, 68.

Ashlyn experienced additional eye-blinking episodes, however, in the weeks following the vaccinations. On August 30, 2000, she became unresponsive for 20 minutes and her extremities jerked uncontrollably. Petitioners immediately called 911. At the emergency room, she was diagnosed as having suffered a grand-mal seizure. Pet. App. 3, 22.

Over the next 17 months, Ashlyn continued to suffer seizures almost daily, at times experiencing three or more seizures in a single day. She also suffered episodes in which her eyes rapidly blinked or fluttered "between 150 and 500 times per day." Pet. App. 3-4. Petitioners sought medical care from several hospitals and numerous doctors, but no treatment proved effective in controlling the seizures. *Id.* at 4, 22-26.

On January 29, 2002, a neurologist at the Mayo Clinic in Rochester, Minnesota, evaluated Ashlyn to determine whether her condition would be susceptible to surgical treatment. The neurologist diagnosed Ashlyn as experiencing "four types of seizures: (1) repeated eye blinking; (2) clonic movement of the face, arm, and leg; (3) generalized seizures with or without focal onset; and (4) partial motor seizures." Pet. App. 4 (emphasis omitted); see *id.* at 96 (neurologist report that "[c]urrently, [Ashlyn] has four types of seizures," one of which is "[r]epeated eye blinking, either unilateral or bilateral with or without head nodding," which "lasts for a few seconds and occurs hundreds of times per day"). The neurologist's evaluation also mentioned that "[i]t was thought that the seizures started seven to ten days after

the 2-month vaccine so no further vaccines were given." *Id.* at 100.

3. a. On August 29, 2003, petitioners filed a claim for compensation under the Vaccine Act, alleging that Ashlyn's severe seizure disorder and intractable epilepsy were caused by the vaccinations administered on July 10, 2000. Pet. App. 4, 26. Based on the petition and an affidavit describing Ashlyn's early symptoms, a special master of the Court of Federal Claims conducted an "onset hearing" to determine whether the petition was timely under Section 300aa-16(a)(2). *Id.* at 4-5, 26-27.

At the hearing, Dr. Jean-Ronel Corbier, a pediatric neurologist, testified for petitioners that a neurological dysfunction likely caused Ashlyn's eye-blinking episode on July 10, 2000, and that the same dysfunction likely triggered the seizure on August 30, 2000. Pet. App. 14-15, 26-27, 74-75.[1] According to Dr. Corbier, the eye-

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[1] See Pet. App. 113 ("[M]y professional opinion is that the time line of when something first started may have started on [July] 10th, that was due to some type of cerebral dysfunction, and then the results culminated in her having a seizure, a generalized tonic, or grand mal seizure as we call it, on August 30th."); *id.* at 115 ("[W]ith progressive dysfunction, [following the eye-blinking episodes] that person then on August 30th had a full-fledged seizure, and went on to have * * * more and more seizures, and you can see that there was a progression of symptoms."); *id.* at 117 ("[O]n that same day you have the eye blinking episodes, irregardless of whether the eye blinking turned out to be some type of cerebral dysfunction or little seizure. And that they progressed on August 30th to a full-blown seizure."); *id.* at 118 ("[W]hat seems likely is that because these were involuntary movements at this stage, that there was some type, of dysfunction going on at that time, that may have led up to something more traumatic or conspicuous, such as the seizure of August 30th."); *id.* at 121 ("[O]ne might say that on July 10th, there were eye blinking episodes that may not necessarily be seizures, but instead some type of cerebral dysfunction that would eventually lead to seizures.").

blinking episodes that preceded Ashlyn's first grand-mal seizure "could have been either one of two things": "small seizures leading up to a big one," or "some type of cerebral dysfunction that would eventually lead to seizures." *Id.* at 121. He testified that, although "eye blinking by itself would not lead necessarily" to a diagnosis of a "seizure disorder[]," eye-blinking episodes "would at least lead to a suspicion and the need for further questioning and evaluation." *Id.* at 114.

Following direct examination of Dr. Corbier, the special master asked him: "[W]ould you say that the first symptom occurred with the eye blinking episodes that were noted on July 10th, or shortly thereafter?" Pet. App. 122. Dr. Corbier replied: "Yes, I think there was some type of dysfunction of some sort that likely started on July 10th, leading to a documented seizure on August 30th." *Ibid.* At the close of Dr. Corbier's testimony, the special master asked him to clarify whether it was his opinion "that the eye fluttering and seizure disorder are both symptoms of a single process caused by an insult to the brain at about the time of the vaccinations." *Id.* at 76-77, 128. Dr. Corbier responded: "Yes, I think that is a likely—that is a good possibility." *Id.* at 77, 28.

Based on Dr. Corbier's testimony, the special master found that the first symptom or manifestation of onset of Ashlyn's seizure disorder was the eye-blinking episode of July 10, 2000. Pet. App. 70-78. Because petitioners filed their Vaccine Act petition on August 29, 2003, more than 36 months after the first symptom or manifestation of onset, see 42 U.S.C. 300aa-16(a)(2), the special master dismissed the petition as untimely. Pet. App. 87.

b. The Court of Federal Claims affirmed. Pet. App. 18-42. It held that the special master was "correct[]" in

finding, based on Dr. Corbier's testimony, that the date of onset was July 10, 2000. *Id.* at 33-34. The court distinguished an earlier, nonbinding decision by a judge of the Court of Federal Claims in *Setnes ex rel. Setnes* v. *United States*, 57 Fed. Cl. 175, 180 (2003) (*Setnes*), which involved an allegation of vaccine-related autism, on the ground that Dr. Corbier's opinion did not conflict with contemporaneous medical evaluations of the first symptoms of the injury. Pet. App. 36. The court also rejected petitioners' proposal for a strictly subjective standard for assessing the occurrence of a "symptom," noting that "the statute of limitations in Vaccine Act cases 'begins to run upon the first symptom or manifestation of the onset of injury, even if the petitioner reasonably would not have known at the time that the vaccine had caused an injury.'" *Id.* at 36-37 (quoting *Brice* v. *Secretary of Health & Human Servs.*, 240 F.3d 1367, 1373 (Fed. Cir.), cert. denied, 534 U.S. 1040 (2001)).

c. The court of appeals affirmed. Pet. App. 1-17. It rejected petitioners' argument that the "symptom or manifestation of onset" of injury must be subjectively recognized as such by the parents to commence the running of the Vaccine Act's statute of limitations. *Id.* at 7-16. Instead, the court held, based on the language of Section 300aa-16(a)(2), that an objectively recognizable symptom or manifestation of onset triggers the start of the limitations period, regardless of whether the petitioner appreciated the medical significance of that symptom at the time. *Id.* at 9 (citing *Shalala* v. *Whitecotton*, 514 U.S. 268, 274 (1995)). Finding no error in the special master's conclusion that the eye-blinking episode on July 10, 2000, was the first symptom of "the same injury that culminated on August 30, 2000, in a grand-mal sei-

zure," the court held that the petition was time-barred. *Id.* at 15.

The court distinguished the Court of Federal Claims' decision in *Setnes* on its facts, noting that "[t]he eye blinking episodes here were not so readily confused with typical child behavior over the course of the limitations period as were the symptoms of autism in *Setnes*." Pet. App. 14; see *id.* at 15 ("[A]s distinguished from *Setnes*, the eye blinking episodes were not normal child behavior."). The court also found that the neurologist's report of January 29, 2002, had made clear to petitioners well in advance of the running of the limitations period "that 'repeated eye-blinking' was not only a symptom of seizure activity but also manifested one type of seizure activity." *Id.* at 14. But the court of appeals also criticized the reasoning of *Setnes*, noting that "it effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was * * * a symptom and manifestation of the injury," and that it incorrectly suggests "that a subtle symptom or manifestation of onset of the injury, such as a symptom that would be recognizable to the medical profession at large but not to the parent, would not be sufficient to trigger the running of the Statute." *Id.* at 10-11.

ARGUMENT

Petitioners contend (Pet. 7) that the court of appeals erred in holding that their petition for compensation under the Vaccine Act was untimely. That contention lacks merit. Section 300aa-16(a)(2) provides that the three-year limitations period runs from "the date of the occurrence of the first symptom or manifestation of onset" of the vaccine-related injury. The court of appeals correctly adopted an objective standard for evaluating

whether a medical condition qualifies as a "symptom or manifestation of onset" of a vaccine-related injury, and its decision does not result in an intra-circuit conflict concerning the statute of limitations in Vaccine Act cases. Further review by this Court is unwarranted.

1. In *Shalala* v. *Whitecotton*, 514 U.S. 268 (1995), this Court considered whether a Vaccine Act petitioner can benefit from the presumption of causation for injuries listed on the Vaccine Injury Table even if some symptoms of the vaccine-related injury predated the vaccination. The court of appeals had concluded that the Vaccine Act did not "expressly" require a showing "that the first symptom of the injury occurred after vaccination." *Id.* at 273-274. This Court reversed, holding that the interpretation by the court of appeals "simply does not square with the plain language of the statute." *Id.* at 274. Construing the same phrase used to define the limitations period in Section 300aa-16(a)(2), the Court noted that "a claimant relying on the table (and not alleging significant aggravation) must show that 'the first symptom or manifestation of the onset . . . of [her table illness] . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.'" *Ibid.* (quoting 42 U.S.C. 300aa-11(c)(1)(C)(i)). By definition, the Court explained, if a symptom or manifestation of the injury occurred before vaccination, then additional symptoms or manifestations after the vaccination "cannot be the first," and cannot "signal the injury's onset." *Ibid.* ("There cannot be two first symptoms or onsets of the same injury.").

In this case, the court of appeals correctly construed the Vaccine Act's statute of limitations in accord with *Whitecotton*. Section 300aa-16(a)(2) provides for a 36-month limitations period that runs from "the date of the

occurrence of the first symptom or manifestation of onset" of the vaccine-related injury. As this Court recognized in *Whitecotton*, the "first symptom or manifestation of the onset" of a vaccine-related injury occurs on the earliest date that the injury results in a symptom or manifestation. See 514 U.S. at 274 (quoting 42 U.S.C. 300aa-11(c)(1)(C)(i)).[2] The court of appeals was therefore correct in holding that "[u]nder the plain language of the Vaccine Act * * * either a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first." Pet. App. 8-9.

Petitioners do not contest the special master's finding (Pet. App. 70-78), affirmed by the Court of Federal Claims (*id.* at 33-34) and the court of appeals (*id.* at 14-15), that Ashlyn's eye-blinking episode on July 10, 2000, resulted from the same neurological disorder that caused her grand-mal seizure on August 30, 2000. Nor do they dispute that, from an objective medical standpoint, that episode was a "symptom" of the disorder. Pet. 4-5 (conceding that "Dr. Corbier testified that Ashlyn's July 10, 2000 eye blinking episode was an 'objective symptom' of a seizure disorder").[3] Instead, petition-

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[2] Although *Whitecotton* addressed the causation standard in Section 300aa-11(c)(1)(C)(i) and this case involves the limitations period in Section 300aa-16(a)(2), both cases turn on the meaning of the same statutory phrase. As the court of appeals recognized, "[t]here is no principled basis" for construing the phrase differently in those provisions. Pet. App. 13.

[3] As the special master observed, petitioners' Vaccine Act petition relied upon Ashlyn's July 10, 2000, eye-blinking episode as crucial evidence that the vaccinations caused her seizure disorder. Pet. App. 12-13, 77-78. Dr. Corbier also pointed to the close temporal relationship between the vaccinations and the initial eye-blinking episode as important evidence causally linking the vaccinations and her injury. *Id.* at 15.

ers urge this Court (Pet. 6-7) to hold that a medical condition qualifies as a "symptom" of a vaccine-related injury only if the parents subjectively recognize it as evidence of the injury, arguing that the court of appeals reached an "absurd result" because, on the day of the vaccinations, petitioners found the eye-blinking episode "completely uneventful, short in duration and meaningless" except as an indication that Ashlyn was tired.

Petitioners' proposed standard finds no support in the text of Section 300aa-16(a)(2). The Vaccine Act uses the term "symptom," which in the context of this case refers to observable physical characteristics of the child, not the parents' appreciation of the medical significance of those characteristics. As the court of appeals recognized, "[a] symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury." Pet. App. 9. That a medical phenomenon does not lead to parental appreciation of the significance of the event does not preclude its classification as a symptom.

Petitioners' proposed exclusion of objective symptoms is particularly implausible in light of the distinction drawn in Section 300aa-16(a)(2) between a "symptom" and a "manifestation of onset" of a vaccine-related injury. The term "manifestation of onset" refers to a medical condition "more self-evident of an injury" than a symptom. Pet. App. 9 (noting that a manifestation of onset may refer to "significant symptoms that clearly evidence an injury"). The Vaccine Act makes clear, however, that the limitations period runs from the occurrence of the first symptom *or* manifestation of onset. 42 U.S.C. 300aa-16(a)(2). The court of appeals correctly held that the limitations period runs from the first

symptom of a vaccine-related injury, whether or not the parents subjectively appreciate its significance at the time.[4]

2. Petitioners also argue (Pet. 8-15) that the decision of the court of appeals conflicts with the decision of the Court of Federal Claims in *Setnes ex rel. Setnes* v. *United States*, 57 Fed. Cl. 175, 180 (2003), resulting in inconsistent standards for autism cases and all other cases. That contention is mistaken.

In *Setnes*, the Court of Federal Claims acknowledged that, under Section 300aa-16(a)(2), the occurrence of either the first "symptom" or "manifestation of onset" triggers the commencement of the limitations period. 57 Fed. Cl. at 179. The court noted, however, that "the beginning stage of autism cannot be reduced to a single, identifiable symptom," and that "[m]any of the initial 'symptoms' are subtle and can easily be confused with typical child behavior." *Ibid.* The court therefore carved out an unwritten exception to the limitations period, reasoning that "[w]here there is no clear start to the injury, such as in cases involving autism, prudence mandates that a court addressing the statute of limitations not hinge its decision on the 'occurrence of the first symptom.'" *Ibid.* (quoting 42 U.S.C. 300aa-16(a)(2)).

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[4] Even if the statutory text were ambiguous, the statute of limitations should be narrowly construed because the Vaccine Act is a limited waiver of the sovereign immunity of the United States. Pet. App. 15; see *Brice* v. *Secretary of Health & Human Servs.*, 240 F.3d 1367, 1370 (Fed. Cir.), cert. denied, 534 U.S. 1040 (2001); *Block* v. *North Dakota ex rel. Bd. of Univ. & Sch. Lands*, 461 U.S. 273, 287 (1983) (because "a statute of limitations * * * constitutes a condition on the waiver of sovereign immunity," courts "must be careful not to interpret it in a manner that would extend the waiver beyond that which Congress intended") (internal quotation marks and citation omitted).

The *Setnes* decision is not binding on the United States Court of Appeals for the Federal Circuit. Pet. App. 8. Indeed, it is not binding even on other judges of the Court of Federal Claims. See, *e.g.*, *Vessels* v. *Secretary of the Dep't of Health & Human Servs.*, 65 Fed. Cl. 563, 569 (2005) ("[T]he decisions of one judge of this Court have no binding effect on the other judges."). Petitioners are therefore incorrect in asserting (Pet. 8) that "as the law exists," autism petitions are subject to a more generous statute of limitations. Decisions of the Federal Circuit are binding on the Court of Federal Claims, and the Federal Circuit has now interpreted the Vaccine Act's statute of limitations in this case. Accordingly, if there is any tension between the Court of Federal Claims' decision in *Setnes* and the Federal Circuit in this case, the latter presumably controls.

Further, the statutory analysis in *Setnes* is incorrect. As the court of appeals recognized, "[a] significant problem with the rationale of *Setnes* is that it effectively reads the Vaccine Act as if the statute of limitations were not triggered until there was appreciable evidence showing a symptom *and* manifestation of the injury." Pet. App. 10. Section 300aa-16(a)(2) provides, however, that the limitations period runs from the first symptom *or* manifestation of onset. *Ibid.* ("The use of the words 'first' and 'or' require that the statute of limitations commence with whichever event (i.e., symptom or manifestation of onset) occurs first."). The Court of Federal Claims erred in *Setnes* in believing that its own sense of "prudence" justified an unwritten exception to that unambiguous text. Cf. *Brice* v. *Secretary of Health & Human Servs.*, 240 F.3d 1367, 1372-1374 (Fed. Cir.) (holding that equitable tolling is unavailable for Vaccine Act petitions, based on Section 300aa-16(a)(2)), cert. denied,

534 U.S. 1040 (2001). The rationale of *Setnes* also conflicts with this Court's decision in *Whitecotton*, which "emphasiz[ed] that *any* observable 'symptom or manifestation' may be the first evidence of injury" and "did not require that a petitioner appreciate the significance of that evidence." Pet. App. 12 (quoting *Whitecotton*, 514 U.S. at 274). In any event, the court of appeals has not yet had an opportunity to review the decision of the Court of Federal Claims in *Setnes*. Pet. App. 38 n.13. The court of appeals should be afforded the opportunity in the first instance to determine whether *Setnes* can be reconciled with the court's decision in this case.

Finally, petitioners could not prevail even under the approach of *Setnes*. That case involved symptoms of autism, such as humming, babbling, and kicking and screaming, so indistinguishable from ordinary child behavior that even "contemporaneous medical evaluations" did not recognize them as symptoms of a medical condition. 57 Fed. Cl. at 181. In this case, by contrast, the repeated episodes in which Ashlyn's eyes rapidly blinked or fluttered "were not so readily confused with typical child behavior." Pet. App. 14; see *id.* at 15 ("[T]he eye blinking episodes were not normal child behavior."). Although petitioners argue that Ashlyn's eye fluttering was recognizable as a symptom of her seizure disorder only in hindsight, see *Setnes*, 57 Fed. Cl. at 180, Dr. Corbier testified that the eye-blinking episodes alone "would at least lead to a suspicion and the need for further questioning and evaluation." Pet. App. 114; see *id.* at 14-15. Thus, even if the reasoning of *Setnes* were correct, it would not assist petitioners.[5]

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[5] Petitioners also argue (Pet. 20-22) that the decision of the court of appeals conflicts with the decision of a special master affirmed on

As the court of appeals observed (Pet. App. 14), the Mayo Clinic neurologist's evaluation of January 29, 2002, made clear to petitioners "that 'repeated eye-blinking' was not only a symptom of seizure activity but also manifested one type of seizure activity." One report also drew an explicit connection between Ashlyn's seizures and the eye-blinking episodes that preceded her first grand-mal seizure: "[i]t was thought that the seizures started seven to ten days after the 2-month vaccine so no further vaccines were given." *Id.* at 100. As of the date of that evaluation, petitioners still had more than 17 months, until July 10, 2003, to file a petition for compensation under the Vaccine Act. Because they waited to file until August 29, 2003, their petition was untimely, and the court of appeals correctly affirmed the decision to dismiss it.

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appeal in *Bradley* v. *Secretary of the Dep't of Health & Human Servs.*, 991 F.2d 1570 (Fed. Cir. 1993). In that case, however, the special master found only that the mother's testimony was not credible and that, in light of conflicting medical testimony, the petitioners had failed to prove by a preponderance of the evidence that those conditions were symptoms of her seizure disorder. *Id.* at 1574-1575. The court of appeals affirmed, holding that those findings were not arbitrary and capricious. *Ibid.* Contrary to petitioners' contention (Pet. 22), *Bradley* does not stand for the proposition that "to establish an onset of injury to prove a table injury claim seems to require contemporaneous medical documentation."

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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